

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Title: **SOLUBILIZED COQ-10**
Inventor: FANTUZZI, Michael
Appln. No.: 10/674,268
Filing Date: September 29, 2003
Dkt. No.: 33503/US
Examiner: KOSSON, Rosanne

DECLARATION UNDER RULE 1.131

I, Michael Fantuzzi, the undersigned, declare as follows:

All statements made herein are true to the best of my knowledge, or if made upon information and belief are believed to be true. I received a Bachelor of Science degree in Biochemistry from the California State University, Los Angeles, in 2006 and had previously attended the University of Southern California School of Pharmacy. I have worked at Soft Gel Technologies, Inc. since 1999 where I am currently a Formulation Chemist and Manager of Research and Development. I am the inventor of the invention disclosed in United States patent application 10/674,268 filed on September 29, 2003 entitled Solubilized COQ-10.

In my declaration of September 27, 2007 I described the process by which I identified that COQ-10 was soluble in limonene. However, for the purpose of clarity, I hereby declare that a focal point of my research was to find a way to solubilize COQ-10 for the purpose of encapsulating COQ-10 in a soft gelatin capsule. Prior to my identification of COQ-10 being soluble in limonene, we had no effective way to solubilize COQ-10 in a non-vegetable oil material. Thus, prior methods of encapsulating COQ-10 were limited. Because one mission of Soft Gel Technologies is to provide efficacious compositions for encapsulation into a soft gel, it is understood that any solution, suspension, mixture or the like that I make is for the purpose of encapsulation within a soft gel. Therefore, as attested in my prior declaration to the U.S. Patent and Trademark Office, when I was originally approached on March 13, 2003 by Lee Ikemoto about identifying effective, new and unappreciated solvents for COQ-10, one focal point of the

research and development request was to develop more effective methods for encapsulating COQ-10 in a soft gel capsule. Thus, the reduction to practice of dissolving COQ-10 in limonene and encapsulation in a soft gel are one and the same. Solvation provided the ability to encapsulate the COQ-10 in a soft gel at much higher concentrations than hitherto possible.

I further note that I stated this in my September 27, 2007 declaration to the Patent Office. "We then conducted research to determine solubility, optimum ranges, and any other co-constituents that may be desirable in a soft-gel capsule." Due to the mission of Soft Gel Technologies, Inc., it would be unrealistic to think that I would conduct research on compositions that were not to be encapsulated in a soft gel capsule.

This declaration is made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and may jeopardize the validity of the subject patent application or any patent issuing therefrom.

Dated: 2/12/08

By: 
Michael Fantuzzi